

REMARKS

Reconsideration of this application is respectfully requested. Claims 1-12 were pending in the application. Claims 1-5 and 10-12 were withdrawn from consideration. Claims 6-9 were rejected. The amendment proposes to amend claim 6. If the amendment proposed above is entered, the claims remaining for consideration will be claims 6-9. No new matter has been added by way of this amendment.

Applicants' representatives would like to express their sincere appreciation for the telephonic discussion held with Examiner Ronald Schwadron on April 27, 2004 as related to the claims under consideration. Accordingly, as discussed with Examiner Schwadron, a Request for Continued Examination is submitted concurrently herewith, and entry of the current amendment is believed to be in order and is requested.

Claims 6-9 were rejected under 35 U.S.C. 112, first paragraph for non-compliance with the written description requirement Applicants have respectfully traversed the Examiner's rejection, and have amended the claims to better clarify the invention. Support for the amended claims can be found in the parent application, U.S. serial number 08/381,528, to which the present application claims priority and which has been incorporated by reference in its entirety, on page 7, lines 18-25, and on page 46 lines 17-25. Further support for the claim amendments can be found in the present application, as the Examiner points out, on page 14, lines 20-22. Withdrawal of the rejection is respectfully requested.

The Examiner has denied the Applicants the benefit of the earlier filing date of parent applications having serial numbers 09/586,704 and 08/381,528, since the claims, as previously amended, fall outside of the scope of the earlier filed applications. Applicants have amended the claims to recite language from the earlier filed applications to which the present application claims priority and have provided support for these amendments, thus retaining the benefit of the earlier filing date as related to the presently amended and claimed invention. Thus, reconsideration of the benefit of the earlier filing date is respectfully requested.

The Examiner has rejected claims 6, 7 and 9 under 35 U.S.C. 102(b) as being anticipated by Steinman et al. (WO 96/23882). Applicants have amended the claims to recite language from U.S. serial number 08/381,528, to which the present application

claims priority and which has been incorporated by reference in its entirety. Accordingly, U.S. serial number 08/381,528 has a priority date of January 31, 1995, which precedes the PCT filing of Steinman et al. by one year and also precedes the publication date of WO 96/23882, which is August 8, 1996. Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 6, 7 and 9 under 35 U.S.C 103(a) as being unpatentable over Steinman et al. (WO96/23882) in view of Black et al. (US patent No. 6,440,418) as applied to claims 6, 7 and 9 and further in view of Siegall (US patent No. 5,541,110). Applicants respectfully traverse the rejection and have amended claim 6 to recite language from U.S. serial number 08/381,528, to which the present application claims priority and which has been incorporated by reference in its entirety. Accordingly, U.S. serial number 08/381,528 has a priority date of January 31, 1995, which precedes the PCT filing of Steinman et al. by one year and also precedes the publication date of WO 96/23882, which is August 8, 1996. Accordingly, Applicants believe the claim amendments render the rejection moot under 35 U.S.C 103(a). Thus, withdrawal of this rejection is respectfully requested.

Rejections Under 35 USC §112, first paragraph

Claims 6-9 were rejected under 35 U.S.C. 112, first paragraph, for not providing adequate written description of the claimed invention. In particular, the Examiner alleges that there is no support in the specification for the claims as previously amended, in that the limitation “and preventing maturation of said dendritic cells ex vivo or in vivo” has been removed. While Applicants respectfully point out to the Examiner that such support is in the application as filed on page 26, lines 16-17 and on page 14, lines 9-22, the claims have been amended to better clarify what Applicants believe to be the invention. In particular, Applicants have amended the claims to recite language from U.S. serial number 08/381,528, to which the present application claims priority and which has been incorporated by reference in its entirety. In particular, Applicants have amended claim 6 to read “under conditions that promote dendritic cell quiescence”. Support for the claim amendment can be found in U.S. serial No. 08/381,528, page 7, wherein lines 18-25 read:

“By targeting an autoantigen or allergen to dendritic cells without including stimulatory agents, *e.g.*, cytokines, lymphokines, or adjuvants, the quiescent dendritic cells can process and present antigen. Presentation of antigen by quiescent dendritic cells is believed to induce antigen-specific T cell anergy or immune tolerance. The autoantigen may be selected from the group consisting of myelin basic protein, collagen or a fragment thereof, DNA, a nuclear protein, a nucleolar protein, a mitochondrial protein, and a pancreatic β -cell protein.”

Further support can be found in U.S. serial No. 08/381,528, on page 46, lines 17-25:

“Alternatively, the present invention provides for inducing tolerance. Tolerance is desirable to avoid detrimental immune responses, in particular, **autoimmunity and allograft rejection. Presentation of antigen by non-activated dendritic cells, *e.g.*, in the skin and T cell areas of the lymphoid organs, induces T cell anergy, and possibly causes destruction of the responder clone. Thus, in one embodiment, **tolerance is induced** by administering an antigen modified by conjugation with a DEC-binding moiety **under conditions that promote dendritic cell quiescence, *e.g.*, in the absence of an infection, without adjuvant, using pyrogen-free pharmaceutical carriers, and in the absence of additional lymphokines or cytokines.**”**

In addition, the present application also refers to the fact that without stimulation of the dendritic cell at the time of antigen presentation, tolerance rather than induction of a cellular response is achieved. The Examiner’s attention is drawn to page 14, lines 20-22 of the present application wherein it states:

“Thus, without dendritic cell stimulation at the time of antigen presentation, tolerance to the delivered antigen rather than induction of a cellular response is achieved.”

Furthermore, Applicants assert that a person skilled in the art would recognize that a quiescent cell is a cell which is at steady state, ie. not activated. Furthermore, agents that activate cells are known to one skilled in the art, and include those outlined in the present application, such as cytokines, lymphokines and adjuvants. In addition, Applicants have provided herein as Exhibit A two sources from an on-line dictionary search, in particular, from dictionary.com and from hyperdictionary.com, in which one of the preferred definitions of the term “quiescent” is “inactive; not active or activated”. As

Applicants have noted above, in the methods of the present application and in the claims as amended, the dendritic cells are maintained under conditions that promote dendritic cell quiescence ie. in conditions that retain the cells in an inactive or not activated state, due to the absence of any stimulants such as lymphokines, cytokines or adjuvants.

In addition, Applicants have further amended claim 6 to better clarify the scope of the invention as it relates to the preselected antigen, wherein the claim now reads on allergens, autoantigens and antigens participating in allograft rejection. Support for this amendment can be found in the parent application, U.S. serial number 08/381,528 on page 7, lines 18-25 and further on page 46, lines 17-19.

Priority

The Examiner alleges that the invention as previously claimed is not disclosed in parent applications 09/586,704 or 08/381,528 and as such, support for the scope of the claimed invention is not provided. Therefore, regarding prior art, the Examiner has set the effective filing date of the instant application as the filing date of the instant application, rather than providing Applicant the benefit of the filing date of the earlier applications.

Applicants respectfully traverse the Examiner's rejection of the earlier filing date and have amended the claims to recite language for which support is provided from the parent application having serial number 08/381,528, filed on January 31, 1995, which has been incorporated by reference in its entirety.

Accordingly, Applicants respectfully request reconsideration of the benefit of the earlier priority date of the parent applications.

Rejections Under 35 USC §102(b)

Claims 6-9 have been rejected under 35 U.S.C. §102(b) as being anticipated by Steinman et al. (WO 96/23882).

Applicants respectfully traverse the Examiner's rejection and have amended the claims to recite language from the parent application, U.S. serial number 08/381,528, to which the present application claims priority and which has been incorporated by reference in its entirety. Accordingly, as noted above, U.S. serial number 08/381,528 has

a priority date of January 31, 1995, which precedes the PCT filing of Steinman et al. by one year and also precedes the publication date of WO 96/23882, which is August 8, 1996. Accordingly, Applicants believe that the claims as presently amended render this rejection moot. Thus, withdrawal of this rejection is respectfully requested.

Rejections Under 35 USC §103(a)

The Examiner has rejected claims 6, 7 and 9 under 35 U.S.C 103(a) as being unpatentable over Steinman et al. (WO96/23882) in view of Black et al. (US patent No. 6,440,418) as applied to claims 6, 7 and 9 and further in view of Siegall (US patent No. 5,541,110). Applicants respectfully traverse the rejection and as noted above have amended claim 6 to recite language from U.S. serial number 08/381,528, to which the present application claims priority and which has been incorporated by reference in its entirety. Accordingly, U.S. serial number 08/381,528 has a priority date of January 31, 1995, which precedes the PCT filing of Steinman et al. by one year and also precedes the publication date of WO 96/23882, which is August 8, 1996. Accordingly, Applicants believe the amendment to the claims renders this rejection moot under 35 U.S.C 103(a). Thus, withdrawal of this rejection is respectfully requested.

Fees

A check in the amount of \$385 is enclosed to cover the Request for Continued Examination. No other fees are believe to be necessitated by this response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or to credit any overpayments.

Conclusion

Applicants believe that the outstanding rejections based on 35 U.S.C. §112 and 35 U.S.C. § 102(b) and 103(a) have been overcome by the claim amendments presented above. Thus, reconsideration and withdrawal of the outstanding grounds of rejection, and allowance of the claims is believed to be in order and is courteously solicited.

In the event that there are any questions concerning this amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned at the number listed below, so that prosecution of the application may be expedited.

Respectfully submitted,



Veronica Mallon, Ph.D.

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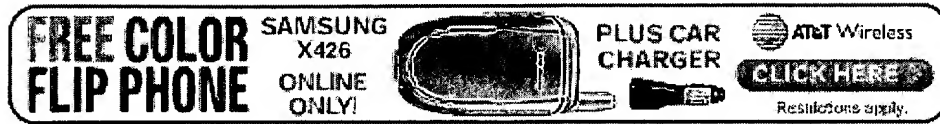
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Attachment: Exhibit A



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Dictionary - [Thesaurus](#)[Get the Top 10 Most Popular Sites for "quiescent"](#)**7 entries found for *quiescent*.**

qui es cent **Pronunciation Key** (kwē-ēs'ənt, kwī-) *adj.*

Being quiet, still, or at rest; inactive. See Synonyms at [latent](#).

[Latin *quiescēns*, *quiescent*- present participle of *quiescere*, *to rest*, from *quies*, *quiet*. See [quiet](#).]

qui es cence *n.***qui es cent ly** *adv.*[\[Download or Buy Now\]](#)

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QUIESCENT: Dictionary Entry and Meaning

Pronunciation: kwī'esunt

Matching Terms: [quiescence](#), [quiescency](#), [Quiescently](#)

WordNet Dictionary

- Definition:**
1. [adj] causing no symptoms; "a quiescent tumor"
 2. [adj] being quiet or still or inactive
 3. [adj] not active or activated; "the quiescent level of centimeter wave-length solar radiation"
 4. [adj] marked by a state of tranquil repose; "the quiescent melancholy of the town"

Synonyms: dormant, inactive, quiet

Webster's 1913 Dictionary

- Definition:**
1. \Qui*es"cent\, a. [L. quiescens, -entis, p. pr. of quiescere: cf. F. quiescent. See {Quiesce}.]
 1. Being in a state of repose; at rest; still; not moving; as, a quiescent body or fluid.
 2. Not ruffled with passion; unagitated; not in action; not excited; quiet; dormant; resting.

In times of national security, the feeling of patriotism . . . is so quiescent that it seems hardly to exist. --Prof. Wilson.
 3. (Gram.) Not sounded; silent; as, y is quiescent in ``day'' and ``say.''
 2. \Qui*es"cent\, n. (Gram.)

A silent letter. --M. Stuart.

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